

IN THE CLAIMS

1. (withdrawn) A method of optimizing clinical diagnosis of a disease using a disease-specific diagnostic algorithm in a programmable automation system which allows the system to self-monitor after performing a clinical test, select the next appropriate test based upon the results obtained, and eliminate unnecessary tests, said method comprising the steps of:

- a) submitting patient tests ordered by a physician to a clinical lab,
- b) using a disease specific algorithm for tests necessary for clinical chemical analysis of a suspected disease or any one of subgroups of the disease in the programmable automation system,
- c) classifying the various subgroups of the suspected disease, said classification based on pathology, pathogenic agent, cause and symptoms,
- d) defining the first set of relevant clinical tests suitable for diagnosing each of the subgroups of the suspected disease classified in c) and eliminating unnecessary tests;
- e) carrying out only the relevant tests defined in d) to obtain at least one clinical test value followed by self-monitoring of the

system to determine a second set of necessary tests;

- f) sequentially running the second set of clinical tests for each of the sub-groups of the suspected disease upon receiving a first set of said clinical test values, and computing the second set of said clinical tests for further testing, and
- g) repeating steps e) and f) to complete the second set of clinical tests computed in f), by self-monitoring of the system until an optimized diagnosis of the specific suspected disease type and group is provided, thereby eliminating unnecessary clinical tests and expensive duplicative procedures, while optimizing an accurate diagnosis using the disease-specific diagnostic algorithm.

2. (withdrawn) The method of claim 1, further comprising performing a different clinical test from tests carried out in steps d) through e) after the values for the tests in steps d) through e) are negative, to rule out a different diagnosis.

3. (withdrawn) The method of claim 1, further comprising running a program code to implement the diagnostic algorithm.

4. (withdrawn) The method of claim 3, further comprising using a modified computer architecture code necessary to implement modifications made in the diagnostic algorithm using the modified computer architecture code.

5. (withdrawn) The method according to claim 1, where said method is the acid fast bacteria algorithm comprising the steps of:

- a) defining the clinical tests used for the diagnosis of acid-fast bacteria;
- b) defining each of the clinical tests listed in (a) and providing the normal value of each clinical test;
- c) sequentially reading out each of said clinical test normal values provided in b);
- d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing, wherein the first of said clinical test values includes auramine smear and the next set of said clinical tests includes amplification; and
- e) receiving a next one of said clinical test, wherein the next of said clinical tests includes organism identification by DNA probe or biochemicals.

6. (withdrawn) The method according to claim 1, wherein said method is the anemia algorithm comprising the steps of:

- a) defining the clinical tests used for the diagnosis of anemia, including myelodysplasia, leukemia, iron deficiency, or B-12/folate deficiency;

- b) defining each of the clinical tests listed in (a) and providing the normal value of each clinical test;
 - c) sequentially reading out each of said clinical test normal values provided in b) ; and
 - d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing, wherein the first of said clinical test values include WBC, MCV, ferritin, B12/folate and the next set of said clinical tests includes smear/image or reticulocyte count, hemoglobin ID, B-12 or folate respectively.
7. (withdrawn) The method according to claim 1, wherein said method is the cardiac risk algorithm comprising the steps of:
- a) defining the clinical tests used for the diagnosis of cardiac risk, including abnormalities in cholesterol, triglycerides, LDL, HDL, homocysteine or anti-cardiolipn;
 - b) defining each of the clinical tests listed in (a) and providing the normal value of each clinical test;
 - c) sequentially reading out each of said clinical test normal values provided in b) ; and
 - d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing, wherein the

first of said clinical test values include cholesterol, HDL, triglycerides and the next set of said clinical tests includes homocysteines anticardio- lipin antibody, LDL by calculation or LDL by direct assay.

8. (withdrawn) The method of claim 1, wherein said method is the HbsAg algorithm comprising the steps of:
 - a) defining the clinical tests used for the diagnosis of HbsAG;
 - b) defining each of the clinical tests listed in (a) and providing the normal value of each clinical test;
 - c) sequentially reading out each of said clinical test normal values provided in b) ; and
 - d) upon receiving a first of said clinical test values, computing the next set of said clinical test for further testing, wherein the first of said clinical test values include prenatal and dialysis specimen measurements of hepatitis B.
9. (withdrawn) The method according to claim 1, wherein said method is the breast cancer algorithm comprising the steps of:
 - a) defining the clinical tests used for the diagnosis of breast cancer including genetic markers;

- b) defining each of the clinical tests listed in (a) and providing the normal value of each clinical test;
 - c) sequentially reading out each of said clinical test normal values provided in b) ; and
 - d) upon receiving a first of said clinical test values, computing the next set of said clinical test for further testing, wherein the first of said clinical test values include cancer marker 15-3, or cancer marker 27-29 and the next set of said clinical tests includes serum bone marker.
10. (withdrawn) The method according to claim 1, wherein said method is the prostate cancer algorithm comprising the steps of:
- a) defining the clinical tests used for the diagnosis of prostate cancer including PSA for no risk, equivocal risk or positive cancer;
 - b) defining each of the clinical tests listed in (a) and providing the normal value of each clinical test;
 - c) sequentially reading out each of said clinical test normal values provided in b); and
 - d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing wherein the

first of said clinical test values include PSA (total) and the next set of said clinical tests includes free PSA or serum bone marker.

11. (withdrawn) The method according to claim 1, wherein said method is the Epstein-Barr virus algorithm comprising the steps of:

- a) defining the clinical tests used for the diagnosis of Epstein-Barr virus, including viral capsid antigen, or Epstein Barr-Virus;
- b) defining each of the clinical tests listed in (a) and providing the normal value of each clinical test;
- c) sequentially reading out each of said clinical test normal values provided in b); and
- d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing wherein the first of said clinical test values include anti-EBV early antigen D, and the next set of said clinical tests includes anti VCA and EBNA.

12. (cancelled)

13. (withdrawn) The method according to claim 1, wherein said method is the thyroid function algorithm comprising the steps of:

- a) defining the clinical tests used for the diagnosis of thyroid dysfunction;
 - b) defining each of the clinical tests listed in (a) and providing the normal value of each clinical test;
 - c) sequentially reading out each of said clinical test normal values provided in b);
 - d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing, wherein the first of said clinical test values include TSH and the next set of said clinical tests includes FT-3 or FT-4.
14. (withdrawn) The method according to claim 1, wherein said method is the autoimmune algorithm comprising the steps of:
- a) defining the clinical tests used for the diagnosis of autoimmune disease including lupus;
 - b) defining each of the clinical tests listed in (a) and providing the normal value of each clinical test;
 - c) sequentially reading out each of said clinical test normal values provided in b);
 - d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing, wherein the

first of said clinical test values include ANA and the next set of said clinical tests includes ds-DNA, HISTONE, Sm respectively, and

- e) receiving a next one of said clinical test of said data word, wherein the next of said clinical tests includes SCL-70, RNP, SSA, SSB, SS-DNA.

15. (withdrawn) The method according to claim 1, wherein said method is the serum protein algorithm comprising the steps of:

- a) defining the clinical tests used for the diagnosis of serum protein defect including serum protein electrophoresis;
- b) defining each of the clinical tests listed in (a) and providing the normal value of each clinical test;
- c) sequentially reading out each of said clinical test normal values provided in b) ; and
- d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing, wherein the first of said clinical test values include serum immuno fixation electrophoresis and the next set of said clinical tests includes quantitative assay of immuno globulin identified by SIFE.

16. (withdrawn) The method according to claim 1, wherein said method is the urinalysis algorithm comprising the steps of:
- a) defining the clinical tests used for the diagnosis urine abnormalities;
 - b) defining each of the clinical tests listed in (a) and providing the normal value of each clinical test;
 - c) sequentially reading out each of said clinical test normal values provided in b); and
 - d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing, wherein the first of said clinical test values include protein, blood, leukocyte esterase ornitrite and the next set of said clinical tests includes microscopic examination of urine.
17. (withdrawn) The method according to claim 1, wherein said method is the human immunodeficiency algorithm comprising the steps of:
- a) defining the clinical tests used for the diagnosis of human immunodeficiency virus;
 - b) defining each of the clinical tests listed in (a) and providing the normal value of each clinical test;

- c) sequentially reading out each of said clinical test normal values provided in b);
 - d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing, wherein the first of said clinical test values include HIV-1 and the next set of said clinical tests includes HIV-1 and HIV-2 respectively, and
 - e) receiving a next one of said clinical test of said data word, wherein the next of said clinical tests includes HIV-2 WB.
18. (cancelled).
19. (withdrawn) The method according to claim 1, wherein said method is the syphilis algorithm comprising the steps of:
- a) defining the clinical tests used for the diagnosis of syphilis;
 - b) defining each of the clinical tests listed in (a) and providing the normal value of each clinical test;
 - c) sequentially reading out each of said clinical test normal values provided in b) ; and
 - d) upon receiving a first of said clinical test values, computing the next set of said clinical test for further testing, wherein the first of said clinical test values include Elisa for T. Pallidum,

and the next set of said clinical tests includes repeat Elisa and the rapid plasma regain test.

20. (withdrawn) The method according to claim 1, wherein said method is the thrombophilia algorithm comprising the steps of:

- a) defining the clinical tests used for the diagnosis of thrombophilia including LA/APA Alg(+) or APC-R(+);
- b) defining each of the clinical tests listed in (a) and providing the normal value of each clinical test;
- c) sequentially reading out each of said clinical test normal values provided in b;
- d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing, wherein the first of said clinical test values include LA-APA Alg(+) or APC-R(+) and the next set of said clinical tests includes homocysteine CRP; and
- e) receiving a next one of said clinical test of said data word, wherein the next of said clinical tests includes Protein C, Protein S or AT-11.

21. (withdrawn) A system for optimizing clinical diagnosis of a disease using a diagnostic algorithm, said system being computer implemented and comprising:
- a) a memory storing component, said component used for storing a set of m clinical tests;
 - b) means of selecting tests necessary to diagnose a suspected disease from tests ordered by a physician;
 - c) means for sequentially reading out each of m clinical tests from said memory, wherein m is an integer greater than one;
 - d) a processor for sequentially programming each of the m clinical tests to produce a complete diagnosis, and for outputting the result.
22. (cancelled)
23. (withdrawn) The system of claim 21, wherein the memory comprises an array of chips, each of which includes a plurality of m -bit storage cells.
24. (withdrawn) The system of claim 23, wherein m equals one.
25. (withdrawn) The method according to claim 1, wherein said method is the lupus algorithm comprising the steps of:

- a) defining the clinical tests for diagnosis of lupus anticoagulant/APA;
- b) defining each of the clinical tests listed in (a) and providing the normal value of each clinical test;
- c) sequentially reading out each of said clinical test normal values provided in b); and
- d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing, wherein the first of said clinical test values include DRVFT and the next set of said clinical tests includes LAC.
- e) from said memory; and
- f) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing, wherein the first of said clinical test values include WBC, MCV, ferritin, B12/folate and the next set of said clinical tests includes smear/image or reticulocyte count, hemoglobin ID, B-12 or folate respectively.

26. (withdrawn) The method of claim 1, wherein the disease-specific diagnostic algorithm comprises a Hepatitis Algorithm.

27. (currently amended) A method of optimizing clinical diagnosis of a disease using a disease-specific diagnostic algorithm in a programmable

automation system which allows the system to self-monitor after performing a clinical test, select the next appropriate test based upon the results obtained, and eliminate unnecessary tests, said method comprising the steps of:

- a) submitting patient tests ordered by a physician to a clinical lab,
- b) selecting a disease specific algorithm for tests necessary for clinical chemical analysis of a suspected disease or any one of subgroups of the disease,
- c) classifying the various subgroups of the suspected disease, said classification based on pathology, pathogenic agent, cause and symptoms,
- d) defining the relevant clinical tests suitable for diagnosing each of the subgroups of the suspected disease classified in c) and eliminating unnecessary tests,
- e) carrying out only the relevant tests defined in d) to obtain at least one clinical test value,
- f) sequentially running a second set of clinical tests for each of the sub-groups of the suspected disease upon receiving a first set of said clinical test values, and computing a second set of said clinical tests for further testing, and
- g) repeating steps e) and f) by self-monitoring of the system until an optimized diagnosis of the specific suspected disease type and group is provided, thereby avoiding unnecessary clinical tests and expensive duplicative procedures, while enabling an accurate diagnosis using the disease-specific diagnostic algorithm,

wherein said method is a hepatitis B algorithm comprising the steps of:

a) i) defining the clinical tests used for the diagnosis of hepatitis

B, including HBsAg, HBsAb or SGPT;

b) ii) defining each of the clinical tests for hepatitis B listed in (a) i) and providing the normal value of each clinical test;

c) iii) sequentially reading out each of said clinical test normal values provided in b) ii);

d) iv) upon receiving a first of said clinical test values, computing a second set of said clinical tests in the diagnostic algorithm for further testing, wherein the first of said clinical test values include HBsAg(+), HBsAg(-)/HBsAb(+) or HBsAg(-)/HBsAb(-), and the second set of said clinical tests includes AFP/HBeAg/Ab, Immune or Hepatitis B(-) respectively,

e) v) receiving a third set of said clinical tests, wherein the third set of said clinical tests includes HBe Ab

f) vi) computing a next portion of the diagnostic algorithm using a fourth set of said clinical tests and a most recently calculated value of a computation of a prior portion of the diagnostic algorithm to produce a fourth clinical test value; and if necessary, repeating steps (e) v) and (f) vi) until all of said clinical tests have been processed, wherein the final value computed for the last clinical test is a value for the complete diagnosis of hepatitis B.